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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/018,251	03/04/2002	Kazuya Hosokawa	2462-131US	6081

7590 06/27/2005

Richard C Woodbridge
Woodbridge & Associates
PO Box 592
Princeton, NJ 08542-0592

EXAMINER

MONDESI, ROBERT B

ART UNIT	PAPER NUMBER
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1653

DATE MAILED: 06/27/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/018,251

Applicant(s)

HOSOKAWA, KAZUYA

Examiner

Robert B. Mondesi

Art Unit

1653

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 08 April 2005.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,4-6 and 8 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1,4-6 and 8 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____.
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

DETAILED ACTION

This office action is in response to amendment filed April 8, 2004. **Claims 1 and 4-6 and 8** as drawn to elected Invention I are currently pending and are under examination.

Withdrawal of Objections and Rejections

The rejection of **claims 1, 4-6 and 8** under 35 U.S.C. 102(b) as being anticipated by Griffin et al. is withdrawn.

The rejection of **claims 1, 4-6 and 8** under 35 U.S.C. 102(a) as being anticipated by Nogami et al., 1999 is withdrawn.

Maintenance of rejections

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claims 1, 4-6 and 8 remain rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

This rejection was explained in the previous Office action.

Claim Rejections - 35 USC § 102

Claims 1 and 6 remain rejected under 35 U.S.C. 102(b) as being anticipated by Berkner et al. WO 92/15686.

This rejection was explained in the previous Office action.

Claim 7 remains rejected under 35 U.S.C. 102(e) as being anticipated by Suzuki et al. United States Patent 5,939,304.

This rejection was explained in the previous Office action.

Response to applicant's arguments

In regards to the rejection of claims 1, 4-6 and 8 under 35 U.S.C § 112, first paragraph, applicants assert that it is not necessary to describe and claim the serine residues this way because their positions are well known.

Applicants' argument has not been found persuasive because active serine residue sites may be known for Factor VII as indicated by WO 92/1586; however active serine residue sites with respect to Factors IX and X are subject to further investigation in the art, for example; Hamamoto et al., 1996 teach that the neutralization of factor VIIa in complex with the cell surface tissue factor by anti-thrombin III-heparin was markedly enhanced by plasma levels of factor X. Active site-mutated factor X (S376A factor X) and factor Xa previously inactivated with dansyl-Glu-Gly-Arg-chloromethyl ketone were as effective as plasma-derived factor X in this reaction, indicating that the active site serine residue of factor Xa was not involved in this mechanism (abstract).

Applicants assert that WO 92/15686 is primarily directed to inhibiting Factor VII by deleting or replacing the active serine residue by means of recombinant genetics and in merely one paragraph modification with chemicals such as sulfonyl fluorides is disclosed, furthermore there are no examples demonstrating the successful inhibition of Factor VII by chemical modification and while WO 92/15686 discloses that Serine 344

of Factor VII was replaced with Ala by means of recombinant genetics, this publication provides inadequate teaching of a method by which Factor VII may be successfully inhibited by chemical modification; therefore the reference is not competent as prior art against the present application for the scope of the subject matter that is presently claimed.

Applicants' arguments have not been found persuasive. The fact that WO 92/15686 teaches all the limitations of the claims is sufficient enough for the reference to anticipate the claims. An anticipatory reference is not required to be of any specific length nor is it required to provide examples. When the reference relied on expressly anticipates or makes obvious all of the elements of the claimed invention, the reference is presumed to be operable. Once such a reference is found, the burden is on applicant to provide facts rebutting the presumption of operability. In re Sasse, 629 F.2d 675, 207 USPQ 107 (CCPA 1980).

In view of rejection of claim 7 under 35 U.S.C. 102(e) as being anticipated by Suzuki et al. United States Patent 5,939,304, the applicants have not submitted an appropriate Declaration; however the applicants have indicated their willingness to submit such declaration should the other outstanding issues be resolved.

Conclusion

No claims are allowed


THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).


A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Robert B. Mondesi whose telephone number is 571-272-0956. The examiner can normally be reached on 9am-5pm, Monday-Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jon Weber can be reached on 571-272-0925. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).


Robert B. Mondesi
Patent Examiner
Group 1653
06-21-05


ROBERT A. WAX
PRIMARY EXAMINER
Art Unit 1653